"As a whole" standard

While the examiner is not limited to the claims in determining the teachings of a prior art reference, reliance on a prior art reference must consider both the applicants' claimed invention and that of the prior art reference "as a whole" including portions that would lead away from the claimed invention. (see MPEP 2141.02 and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). In addition, such reliance on the entirety of the prior art reference resides in what that reference "...would have ***reasonably suggested*** to one having ordinary skill in the art, including non-preferred embodiments." (MPEP 2123).

When reading the Beerse et al. patent without benefit of the applicants specification and claims, it is clear that their invention when considering their reference "as a whole" is directed towards compositions which must contain: (1) a "safe and effective" amount of a benzoic acid analog and a metal salt (or a metal-benzoic acid analog complex) ; and (2) a dermatologically acceptable carrier with a pH of from about 1 to about 7 and being substantially free of para-amino salicylic acid. This differs greatly from the invention claimed by the applicants, i.e. only the "dermatologically acceptable carrier" limitation could arguably be considered to be a requirement of the applicants' claimed invention.

Improper to "pick and choose" elements

In order to modify the Beerse et al. reference to approach the applicants' invention, one of ordinary skill in the art would have to turn to the voluminous number of additional ingredients cited over 37 columns (out of a 62 column patent) of the specification (i.e. col. 8-44). However, It has previously been held that ***"[i]t is impermissible*** within the framework of section 103 ***to pick and choose*** from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (see *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965))

More recently, it has been held that "...***'Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention***.' see *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998).

There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person or ordinary skill in the field of invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. see *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000); *ATD Corp.*, 159 F.3d 546, 48 USPQ2d 1329; *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ('When the patented invention is made by combining known components to achieve a new system, ***the prior art must provide a suggestion or motivation*** to make such a combination.')" see *Crown Operations Int'l., Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 62 USPQ2d 1917 (Fed. Cir. 2002).

- No recognition by prior art that parameter is a result-effective variable;
- "Well within the skill of an artisan" is not the proper standard for determination of a *prima facie* case of obviousness

The examiner stated that "optimization of amounts of ingredients in a cosmetic compositions (sic) is considered well within the skill of an artisan, involving merely routine skill in the art."

However, MPEP 2144.05 section II (Optimization of Ranges) states that "***A particular parameter must first be recognized as a result-effective variable***, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)." Beerse et al. does not teach or suggest that the use of Aristoflex AVC is a result-effective variable either within the context of their own invention or that of the applicants.

In addition, MPEP 2143.01 states that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were known in the art is not sufficient to establish a *prima facie* case of obviousness ***without some objective reason to combine the teachings of the references***. *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993)." (or in this case to modify the singly reference)

Claims 4, 5, 7 and 8 were rejected by the examiner as being obvious over Beerse et al., *ibid.*, in view of the applicants alleged admission regarding the prior art in the specification at pages 14-19.

The applicants' comments to the Beerse et al. reference made above would also apply here and these claims would stand or fall with the appropriateness of using the Beerse et al. reference for claims 1-3 and 6.

With regard to the statement by the examiner that "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further comprise one or more dyes coloring pigments in the compositions." (page 4, second to last paragraph of office action), the examiner is reminded that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious ***unless the prior art also suggests the desirability of the combination***." see also *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430, (Fed. Cir. 1990). The Beerse et al. reference suggests no particular desirability or preference for the infinite number of compounds/ingredients cited in col. 8-44 of their specification.

With regard to the statement by the examiner that "...since adding dyes coloring pigments to a cosmetic composition is well known in the art and is considered conventional in the competence level of an ordinary skilled artisan in cosmetic science.", the last paragraph of the response to the rejection of claims 1-3 and 6 is to be considered repeated here.

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (6 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: **16 January 2003**

By: _____
Vilma I. Fernandez

COPY OF CLAIMS SHOWING AMENDMENTS MADE

1. A cosmetic or dermatological emulsion of the oil-in-water type, comprising
   (i) up to 90% by weight of a water phase,
   (ii) up to 40% by weight of a lipid phase, based on the total weight of the preparation,
   (iii) up to 10% by weight of one or more emulsifiers, ***and***
   (iv) **[also comprising]** up to 5% by weight of one or more ammonium acryloyldimethyltaurates/vinylpyrrolidone copolymers.

2. The emulsion as claimed in claim 1, wherein its lipid content is in the range from 0.5% by weight to 20% by weight.

3. The emulsion as claimed in claim **[6]** ***2***, wherein its lipid content is up to 7.5% by weight.

4. The emulsion as claimed in claim 1, further comprising one or more dyes, coloring pigments, or a combination thereof.

5. The emulsion as claimed in claim 4, wherein the total amount of the dyes and coloring pigments is from 0.1% by weight to 30% by weight based on the total weight of the preparations.

6. The emulsion of claim **[1]** ***2***, wherein said lipid content is 5-10% by weight.

7. The emulsion of claim **[4]** ***5***, wherein said amount of dyes and coloring pigments is from 0.5 to 15% ***by weight***.

8. The emulsion of claim 7, wherein said amount of dyes and coloring pigments is from 1.0 to 10% ***by weight***.